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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/669,392

09/24/2003

Richard Boydston North

1023-306US03

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,392

Applicant(s)

SPELMAN ET AL

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-45 and 60-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-45, 60-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/11/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I in the reply filed on 11/1/06 is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 3/11/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the references lack a date of publication. It has been placed in the application file, but the information referred to therein for those references has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-45 and 69-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, line 2, "an implantable neurostimulator" is inferentially included and it is unclear if the applicant is positively reciting the stimulator or functionally reciting the stimulator. The examiner has interpreted the claim as functionally reciting the stimulator and it is suggested

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to state “wherein the device is adapted to control the implantable neurostimulator...” to functionally recite the stimulator. In addition, “a plurality of stimulation settings” is inferentially included and the examiner has interpreted the claim as positively reciting the settings. It is suggested to first positively recite the setting before they are used in a connection in the claim. The use of “according to at least one user-chosen criteria” is inferentially included and is vague since no element has been set forth to accept a user chosen criteria.

In claim 37, it is suggested to use “wherein the device is adapted to automatically...”.

In claim 40, line 3, “an implantable...” should be “the implantable...” since the stimulator is recited in line 1.

In claim 69, line 4, “interface receives an indication” should be “interface adapted to receive...” since the indication is not being positively recited. In addition, “the computing device” lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-24, 26-33, 36-38, 40-42, 44, 45, 63, 67, 68, 73,75, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Torgenson et al (5893883). Torgenson discloses displaying of the stimulation settings (e.g. figures 3-7, col. 5) and ordering of the list (e.g. col. 8,

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lines 7-23, col. 10, lines 51-60), retesting the parameters (e.g. col. 11, line 42) and storing the collected information in a memory/database in a portable device (e.g. col. 3)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-45, 63-68, and 73-76 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Law et al (5938690).

Law discloses the use of presenting/displaying a list of stimulation settings to an operator (e.g. abstract, col. 7, 30-60, etc) and ordering the list according to user chosen criteria, such as parathesia map drawing (e.g. col. 12, lines 15-30, col. 14, lines 1-15), in that other settings are eliminated or that a score is given to the setting for evaluation to determine the most effective setting. In addition, Law discloses the use of the different settings, such as electrode, polarity,

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pulse width, frequency, etc (e.g. col. 7, 30-60, col. 11, etc), the drawing of pain maps (e.g. col. 3), parathesia maps (e.g. figures 7, 8, col. 3, etc), providing the collected information to a database as storing the information in the computer (and e.g. col. 13, line 33), retesting at least one stimulation setting (e.g. col. 13, lines 17-52), and determining whether the amplitude falls within boundaries (e.g. col. 8, lines 35-70).

In the alternative, Law discloses the claimed invention except for ordering the list according to numeric rating information, retesting at least one stimulation setting based on the user-chosen criteria, and determining whether the rating information falls within boundaries based on the threshold amplitude values. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the stimulation system and method as taught by Law, the use of ordering the list according to numeric rating information, retesting at least on stimulation setting based on the user-chosen criteria, and determining whether the rating information falls within boundaries based on the threshold amplitude values since such a modification would provide a stimulation system and method with: ordering the list according to numeric rating information to allow a comparison between the results to provide the most effective stimulation setting to the patient; retesting at least one stimulation setting based on the user-chosen criteria to compare to settings to determine which setting is the best and to check if the setting was previously accurately assessed; and determining whether the rating information falls within boundaries based on the threshold amplitude values to provide the correct amplitude value to provide proper pain relief.

Claims 28, 37, and 45 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Law or Torgenson.

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Both Law and Torgenson discuss the use of the microprocessor/computer selecting settings to be applied to the system to deliver the stimulation and therefore would automatically program the implantable device (e.g. cols. 13 and 14 in law, cols. 8, 10, and 11 in Torgenson).

In the alternative, Law or Torgenson do not disclose the use of automatically programming the implantable device with one of the stimulation settings based on the user-chosen criteria. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation system and method as taught by Law or Torgenson, with the automatic programming of the implantable device with one of the stimulation settings based on the user chosen criteria since it was known in the art that stimulation systems and methods use the automatic programming of the stimulation settings based on the user chosen criteria to automate a previously known manual activity that reduces the chance of user error and increases the speed at which the task can be accomplished.

Claims 60-62 and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Law or Torgenson in view of Fowler et al (5370672 or "Patient Interactive PC interface to implanted, multichannel stimulators"). Law or Torgenson disclose the claimed invention except for the storing the programming codes, identifying a type of neurostimulator, selecting a programming code based on the neurostimulator, and transmitting the code to the stimulator by using a transistorized transmitter and antenna to modulate a carrier signal based on retrieved parameter to program the stimulator. Fowler teaches that it is known to use an IBM computer, with transmitter and antenna and would necessarily store the programming codes, identify a type of neurostimulator, select a programming code based on the neurostimulator, and transmit the

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code to the stimulator by using a transistorized transmitter and antenna to modulate a carrier signal based on retrieved parameter to program the stimulator to allow the system to work with several different types of neurostimulators so that multiple programmers are not necessary. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation system as taught by Law or Torgenson, with the storing the programming codes, identifying a type of neurostimulator, selecting a programming code based on the neurostimulator, and transmitting the code to the stimulator by using a transistorized transmitter and antenna to modulate a carrier signal based on retrieved parameter to program the stimulator as taught by Fowler, since such a modification would provide a stimulation system and method with one programmer that can program multiple different implantable systems and reduce the complexity of using and cost of buying several different programmers .

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 20-45 and 60-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6308102 in view of Law or Torgenson and Fowler. The patented claims are narrow and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the ordering, maps, transmitter, etc in view of Law or Torgenson and Fowler (as discussed above) since it provides a stimulation system and method that can choose the most effective stimulation pattern to apply to the patient using a single programming device.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

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GRE
May 14, 2007